

REMARKS

The foregoing amendments and these remarks are in response to the Office Action dated August 11, 2006. Applicant hereby requests a three month extension of time. Authorization to charge the extension fees to Deposit Account No. 50-0951 is attached hereto.

At the time of the Office Action, claims 1-16 were pending. In the Office Action, objections were raised to the drawings, abstract and specification. Claims 1, 2 and 5-16 were provisionally rejected on the ground of non-statutory obviousness-type double patenting. Claims 1, 3, 4-12 and 14-16 were rejected under 35 U.S.C. §103(a). The objections and rejections are discussed in more detail below.

I. Objections to the Abstract and Specification

In the Office Action, the abstract was objected to because it was alleged to refer to purported merits or speculative applications of the invention, and because it was more than 150 words. The specification was objected to for the informalities listed in the Office, namely the use of incorrect reference numbers. Appropriate corrections are made to the abstract and specification herein, and withdrawal of the objections is thus respectfully requested.

II. Objections to the Drawings

An objection was raised to the drawings for failing to include reference numbers 16 and 17 mentioned in the specification. Also, the drawings were objected to for failing to show every feature of the invention specified in the claims. More specifically, the intermediate plate element being an open washer integrally formed with a flange portion as stated in claim 13 and the hole closer to the screw head includes a partial thread as stated in claim 2 were required to be shown or the features cancelled from the claims.

Applicant respectfully submits that the intermediate plate element being an open washer (namely an open ring of metal, which defines a central semi-circular hole) is clearly shown in figures 10, 11, 13 and 14 in connection with the description page 8, line 20 to page 9 line 6.

Essentially, the plate shown in figures 10, 21, 13, and 14 may be considered as an open washer integrally formed with a flange portion 21, namely an open ring having an integrally formed flange portion. Also the transversal hole nearest the head of the screw comprising at least a partial thread, namely hole 6', is shown in figure 1 in connection with page 6 lines 18-24 and figures 4 and 5.

Replacement drawings which include reference numbers 16 and 17 are enclosed.
Withdrawal of the objection is thus respectfully requested.

III. Double Patenting Rejection

Claims 1, 2 and 5-16 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11, 13 and 14 of copending U.S. Patent Application No. 10/526,364. A terminal disclaimer is filed herewith to overcome the rejection based upon U.S. Patent Application Nos. 10/526,364. The Commissioner is hereby authorized to charge the terminal disclaimer fee to Deposit Account No. 50-0951.

IV. Rejections on Art

Claims 1, 3, 4-6, 14 and 15 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 3,799,218 to Halloran (hereafter "Halloran") in view of U.S. Patent No. 6,270,499 to Leu (hereafter "Leu"). Claims 7-12 and 16 are rejected under 35 U.S.C. §103(a) as being unpatentable over Halloran in view of Leu and in further view of U.S. Patent No. 6,692,498 to Niiranen (hereafter "Niiranen").

Applicant has amended claim 1 to recite that the threaded portion of the proximal hole of the nail engages the threaded portion of the locking screw at least in a crest to crest fashion. The "crest to crest" engagement consists of an occasional engagement, which occurs between the screw and the hole only in case of minimal displacement of the bone, as disclosed on page 4 lines 3-7. Essentially, the "crest to crest" engagement can be easily removed by slightly moving the thread (crest) of the screw away from the thread (crest) of the hole. Therefore, the disengagement of the screw and the hole is obtained without removing the screw out from the threaded hole. The partially threaded portion works as a portion of nut screw, but does not interfere with the screw during normal insertion. Such a "crest to crest" engagement between the intramedullary fixation

element and the screw is particularly suitable for the fracture pattern on the humeral head or humeral proximal portion.

It should be noted that the fracture pattern on the humeral head is unique and provides several fracture fragments. In particular this fracture pattern on the humeral head requires a freedom in the choice of screw direction, in order to accommodate several fracture fragments. The "crest to crest" engagement between the screw and the nail permits such a freedom, because the engagement is independent from the screw insertion, and therefore from the screw direction.

Halloran discloses a system comprising an intramedullary fixation element and screws. The screw comprises a screw head and a screw body with a constant pitch and a thread diameter smaller than the diameter of the holes located in the intramedullary fixation element. The intramedullary fixation element includes at least one proximally transverse hole that comprises opposite holes located on opposite sides of the intramedullary fixation element.

Notably, Halloran does not disclose that the hole comprises an internally threaded portion, which is a portion of nut screw or a knurl portion. Therefore, Halloran teaches away from providing any engagement between the screw and the intramedullary fixation element. As such, there is no teaching or suggesting on in Halloran to use an intramedullary implant for the osteosynthesis of the humeral head with several fracture fragments, by means of an engagement between the intramedullary fixation element and the screw in any direction. Moreover, it is clearly shown that the system of Halloran is not adapted for the proximal portion of the bone. In fact, the screws of Halloran are on the diaphysis and not on the proximal portion of the bone. In addition, in Halloran, the intramedullary fixation element is not a cannulated nail.

With regard to Leu, this reference teaches an intramedullary fixation element that comprises a proximally transverse hole having an internal thread, which is shown in the attached piece shown in figure 2 of this patent, and a locking screw firmly inserted therein. In Leu, the threaded portion of the screw is firmly screwed into the proximally transverse hole of the nail, and this engagement can be removed only by completely unscrewing the screw from the proximal hole. Therefore, the disengagement is obtained only by removing the screw out from the threaded hole. Accordingly, Leu discloses a proximally transverse hole of the intramedullary fixation element, which is able to engage the threaded portion of the screw, neither occasionally in case of

minimal displacement of the bone nor in the removable manner explained above. As a consequence, Leu teaches away from an occasional "crest to crest" engagement. Moreover, in Leu, the threaded portion does interfere with the screw insertion.

Therefore, the engagement of Leu forces only one screw direction, whereas by means of the "crest to crest" engagement recited in claim 1, there is the freedom in the choice of screw direction which is required for the use of the system on the humeral head or proximal portion of the bone. Thus, the Leu design also lacks any flexibility required for treatment of comminuted proximal portion fractures, such as humeral head fractures.

With regard to Niiranen, this reference relates to plates independent from intramedullary nails and therefore has little in common with the present application. Moreover, Niiranen shows only a Y-shaped plate. The Y-shaped plate does not have the same shape and outline of the plate of the present application, namely an open washer integrally formed with a flange portion.

The Y-shaped plate of Niiranen does not define any central semi-circular hole for the accommodation of the screw, but only a V-shaped seat. Whenever the Y-shaped plate is placed astride of a locking screw, the shaft of the locking screw will be placed in the V-shaped seat. This V-shaped seat only provides two points of contact between the plate and the screw shaft, and therefore a stable accommodation of the screw cannot be ensured. Thus, the Y-shaped plate of Niiranen is not suitable for being used in connection with a screw. Moreover, the Y-shaped plate of Niiranen cannot slide safely on an already inserted screw.

Therefore, the Y-shaped plate of Niiranen teaches away from the need for allowing the insertion of an open washer under a locking screw, by sliding the entire plate under the already inserted screw. As a consequence, the Y-shaped plate of Niiranen cannot permit at all the insertion of a screw in multiple directions, which is required for the use on the humeral head or proximal portion of the bone.


For the foregoing reasons, claim 1 is believed to be patentable, and in condition for allowance, and applicant traverses the rejection thereof. The dependent claims are believed to be allowable because of their dependence upon an allowable base claim, and because of the further features recited.

V. Conclusion

Applicants have made every effort to present claims which distinguish over the prior art, and it is thus believed that all claims are in condition for allowance. Nevertheless, Applicants invite the Examiner to call the undersigned if it is believed that a telephonic interview would expedite the prosecution of the application to an allowance. In view of the foregoing remarks, Applicants respectfully request reconsideration and prompt allowance of the pending claims.

Respectfully submitted,

Date: 2-9-07



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